AMENDMENTS TO THE CLAIMS

The following listing of claims replaces all prior versions and listings of claims.

1. (Original): An impedance catheter for measuring luminal cross-sectional area of blood vessels, heart valves, and other hollow visceral organs, for enabling selection of an appropriately sized stent or other medical device and for avoiding under or over deployment and under or over sizing of the stent or other medical device, comprising:

an elongated tubular body extending from a proximal body end to a distal body end, said body having an exterior surface and defining a first lumen along the longitudinal axis of the body, whereby enabling introduction of the catheter into a treatment site;

a first excitation impedance electrode and a second excitation impedance electrode along the longitudinal axis of the body, both located near the distal body end, said first excitation electrode comprising a first excitation impedance lead extending from said first excitation electrode to a data acquisition system near the proximal body end, said second excitation electrode comprising a second excitation impedance lead extending from said second excitation electrode to the data acquisition system;

a first detection impedance electrode and a second detection impedance electrode along the longitudinal axis of the body, both located in between the first and second excitation electrodes, said first detection electrode comprising a first detection impedance lead extending from said first detection electrode to the data acquisition system, said second detection electrode comprising a second detection impedance lead extending from said second detection electrode to the data acquisition system; and

a first suction/infusion port located near the distal end, wherein said first suction/infusion port is in communication with said first lumen, whereby enabling injection of two or more solutions into the treatment site;

wherein at least one of the first and second excitation electrodes are in communication with a constant current source, whereby enabling supply of constant electrical current to the treatment site, whereby enabling measurement of two or more conductance values at the treatment site, and whereby enabling calculation of cross-sectional area at the treatment site.

2. (Original): A system for measuring luminal cross-sectional area of blood vessels, heart valves, and other hollow visceral organs, for enabling selection of an appropriately sized

stent or other medical device and for avoiding under or over deployment and under or over sizing of the stent or other medical device, comprising:

an impedance catheter extending from a proximal catheter end to a distal catheter end, said catheter capable of being introduced into a treatment site, said catheter further comprising:

a suction/infusion port near the distal catheter end;

two or more excitation electrodes; and

two or more detection electrodes;

a solution delivery source for injecting a solution through the catheter, through the suction/infusion port and into the treatment site, whereby enabling injection of two or more solutions into the treatment site;

a constant current source in communication with at least one of the excitation electrodes, whereby enabling supply of constant electrical current to the treatment site; and

a data acquisition and processing system in communication with the detection electrodes, whereby enabling measurement of two or more conductance values at the treatment site, and whereby enabling calculation of cross-sectional area at the treatment site.

3. (Original): An impedance catheter, comprising:

an elongated tubular body extending from a proximal body end to a distal body end, said body having an exterior surface and defining a first lumen along the longitudinal axis of the body;

a first excitation impedance electrode and a second excitation impedance electrode along the longitudinal axis of the body, both located near the distal body end, said first excitation electrode comprising a first excitation impedance lead extending from said first excitation electrode to a data acquisition system near the proximal body end, said second excitation electrode comprising a second excitation impedance lead extending from said second excitation electrode to the data acquisition system;

a first detection impedance electrode and a second detection impedance electrode along the longitudinal axis of the body, both located in between the first and second excitation electrodes, said first detection electrode comprising a first detection impedance

lead extending from said first detection electrode to the data acquisition system, said second detection electrode comprising a second detection impedance lead extending from said second detection electrode to the data acquisition system; and

a first suction/infusion port located near the distal end, wherein said first suction/infusion port is in communication with said first lumen.

4. (Original): The impedance catheter of Claim 3, wherein the first lumen is in communication with a source of a solution to be injected through the first lumen, through the first suction/infusion port into a targeted treatment site.

5. (Original): The impedance catheter of Claim 4, wherein the solution comprises an NaCl solution.

6. (Original): The impedance catheter of Claim 3, further comprising a first pressure port along the longitudinal axis of the elongated body, located near the distal end, wherein said first pressure port is in communication at least one pressure conduit, wherein said pressure conduit is in communication with a pressure transducer.

7. (Original): The impedance catheter of Claim 3, further comprising:

a second lumen defined by the body and located along the longitudinal axis of the body; and

an inflatable balloon along the longitudinal axis of the elongated body, located near and proximal relative to the first suction/infusion port, wherein the inflatable balloon extends from a balloon proximal end to a balloon distal end, wherein the inflatable balloon is in communication with the second lumen.

8. (Original): The impedance catheter of Claim 7, wherein the second lumen is in communication with a balloon inflation control device.

9. (Original): The impedance catheter of Claim 7, further comprising:

a third excitation impedance electrode and a fourth excitation impedance electrode along the longitudinal axis, both located between the proximal balloon end and the distal balloon end, said third excitation electrode comprising a third excitation impedance lead extending from said third excitation electrode to the proximal body end, said fourth excitation electrode comprising a fourth excitation impedance lead extending from said fourth excitation electrode to the proximal body end; and

a third detection impedance electrode and a fourth detection impedance electrode along the longitudinal axis of the body, both located in between the third and fourth excitation electrodes, said third detection electrode comprising a third detection impedance lead extending from said third detection electrode to the proximal body end, said fourth detection electrode comprising a fourth detection impedance lead extending from said fourth detection electrode to the proximal body end.

10. (Original): The impedance catheter of Claim 7, further comprising a second suction/infusion port located between the proximal balloon end and the distal balloon end, wherein said second suction/infusion port is in communication with said first lumen.

11. (Original): The impedance catheter of Claim 3, further comprising an ultrasound transducer near the distal end of the elongated body.

12. (Original): The impedance catheter of Claim 7, further comprising a stent located over the balloon, said stent capable of being distended and implanted into the treatment site.

13. (Currently amended): A system for measuring [[the]] a cross-sectional area of a targeted treatment site, comprising:

an impedance catheter extending from a proximal catheter end to a distal catheter end, said catheter further comprising a suction/infusion port near the distal catheter end;

a solution delivery source for injecting a solution through the catheter, through the suction/infusion port and into the treatment site;

a constant current source; and

a data acquisition and processing system that receives conductance data from the catheter and determines the cross-sectional area of the treatment site.

14. (Original): The system of Claim 13, wherein the data acquisition processing system further comprises a processing unit.

15. (Original): The system of Claim 13, wherein the data acquisition processing system further comprises a personal computer.

16. (Original): The system of Claim 13, wherein the solution comprises an NaCl solution.

17. (Original): The system of Claim 13, wherein the treatment site comprises a body lumen.

18. (Original): The system of Claim 13, further comprising a fluid heating unit in communication with the fluid delivery source.

19. (Original): The system of Claim 13, wherein the catheter further comprises an inflatable balloon along its longitudinal axis.

20. (Original): The system of Claim 13, wherein the catheter further comprises a pressure transducer near the distal catheter end.

21. (Original): The system of Claim 20, wherein the data acquisition and processing system receives pressure data from the pressure transducer and determines the cross-sectional area of the treatment site.

22. (Currently amended): A method for measuring [[the]] a cross-sectional area of a targeted treatment site, comprising:

introducing an impedance catheter into a treatment site;

providing constant electrical current flow to the treatment site through the catheter;

injecting a known volume of a first solution of a first compound having a first conductivity into the treatment site;

measuring a first conductance value at the treatment site;

injecting a second solution of a second compound having a second conductivity into the treatment site, wherein the second volume is equal to the first volume, and wherein the second conductivity does not equal the first conductivity;

measuring a second conductance value at the treatment site;

calculating the cross-sectional area of the treatment site based on the first and second conductance values and the conductivities of the first and second compounds.

23. (Original): The method of Claim 22, wherein the treatment site comprises a body lumen.

24. (Original): The method of Claim 23, wherein the body lumen comprises a blood vessel.

25. (Original): The method of Claim 23, wherein the body lumen comprises a biliary tract.

26. (Original): The method of Claim 23, wherein the body lumen comprises the esophagus.

27. (Original): The method of Claim 26, wherein the step of injecting a first solution of a first compound comprises the step of administering said first solution to a patient orally.

28. (Original): The method of Claim 26, wherein the step of injecting a second solution of a second compound comprises the step of administering said second solution to a patient orally.

29. (Original): The method of Claim 22, wherein the first compound is NaCl.

30. (Original): The method of Claim 22, wherein the second compound is NaCl.

31. (Original): The method of Claim 22, further comprising the step of selecting the catheter to be introduced into the treatment site based on the measurement of a first conductance and a first current density at the treatment site.

32. (Original): The method of Claim 31, further comprising the step of calculating a first nodal voltage and a first electrical field based on the first conductance and the first current density.

33. (Original): The method of Claim 32, further comprising the steps of:

applying finite element analysis to the first nodal voltage and first electrical field values;

determining the appropriate catheter dimensions for minimizing nonparallel electrical field lines at the treatment site; and

selecting an appropriately-sized catheter for introduction into the treatment site.

34. (Original): The method of Claim 33, wherein the step of finite element analysis is performed using a finite element software package.

35. (Original): The method of Claim 22, wherein the catheter comprises an inflatable balloon along the longitudinal axis of the catheter.

36. (Original): The method of Claim 35, further comprising the step of inflating the balloon to breakup any materials causing stenosis at the treatment site.

37. (Original): The method of Claim 35, wherein the catheter further comprises a stent located over the balloon, said stent capable of being distended to the desired lumen size and implanted into the treatment site.

38. (Original): The method of Claim 37, further comprising the steps of:

distending the stent by inflating the underlying balloon; and

releasing and implanting the stent into the treatment site.

39. (Original): The method of Claim 22, further comprising the steps of:

selecting an appropriately-sized stent based on the cross-sectional area value of the treatment site; and

implanting the stent into the treatment site.

40. (Original): The method of Claim 22, wherein the catheter comprises a pressure transducer.

41. (Original): The method of Claim 40, further comprising the steps of:

measuring a first pressure gradient value from the pressure transducer near the treatment site; and

calculating the cross-sectional area of the treatment site based in part on the first gradient pressure value.

42. (Original): A method for constructing a three-dimensional model of a treatment site, comprising:

introducing an impedance catheter into the treatment site;

measuring the a first cross-sectional area at a first point along the longitudinal axis;

pulling back the catheter to a second point along the longitudinal axis at a first speed, wherein the second point is located proximally relative to the first point along the longitudinal axis;

measuring a second cross-sectional area at the second point along the longitudinal axis; and

constructing a three-dimensional model of the treatment site along the longitudinal axis based in part on the first and second cross-sectional area measurements.

43. (Original): The method of Claim 42, further comprising the steps of:

pulling back the catheter to a third point along the longitudinal axis at a second speed, wherein the third point is located proximally relative to the second point along the longitudinal axis, wherein the second speed is equal to the first speed;

measuring a third cross-sectional area at the third point along the longitudinal axis; and

constructing a three-dimensional model of the treatment site along the longitudinal axis based in part on the third cross-sectional area measurement.

44. (Original): The method of Claim 42, wherein the treatment site comprises a body lumen.

45. (Original): The method of Claim 44, wherein the body lumen comprises a blood vessel.

46. (Original): A method for constructing a three-dimensional model of a treatment site, comprising:

introducing an impedance catheter into the treatment site;

measuring the a first cross-sectional area at a first point along the longitudinal axis;

pushing forward the catheter to a second point along the longitudinal axis at a first speed, wherein the second point is located distally relative to the first point along the longitudinal axis;

measuring a second cross-sectional area at the second point along the longitudinal axis; and

constructing a three-dimensional model of the treatment site along the longitudinal axis based in part on the first and second cross-sectional area measurements.

47. (Original): The method of Claim 46, further comprising the steps of:

pushing forward the catheter to a third point along the longitudinal axis at a second speed, wherein the third point is located distally relative to the second point along the longitudinal axis, wherein the second speed is equal to the first speed;

measuring a third cross-sectional area at the third point along the longitudinal axis; and

constructing a three-dimensional model of the treatment site along the longitudinal axis based in part on the third cross-sectional area measurement.

48. (Original): The method of Claim 46, wherein the treatment site comprises a body lumen.

49. (Original): The method of Claim 48, wherein the body lumen comprises a blood vessel.

50. (New): An impedance catheter assembly, comprising:

an elongate wire extending from a proximal wire end to a distal wire end;

a catheter comprising an elongate tube extending from a proximal tube end to a distal tube end, said tube having an exterior surface and defining a tube lumen along the longitudinal axis of the tube, said tube surrounding the wire coaxially;

a first excitation impedance electrode and a second excitation impedance electrode along the longitudinal axis of the wire, both located near the distal wire end, said first excitation electrode comprising a first excitation impedance lead extending from said first excitation electrode to a data acquisition system near the proximal wire end, said second excitation electrode comprising a second excitation impedance lead extending from said second excitation electrode to the data acquisition system; and

a first detection impedance electrode and a second detection impedance electrode along the longitudinal axis of the wire, both located in between the first and second excitation electrodes, said first detection electrode comprising a first detection impedance lead extending from said first detection electrode to the data acquisition system, said second detection electrode comprising a second detection impedance lead extending from said second detection electrode to the data acquisition system.

51. (New): The assembly of Claim 50, wherein the wire comprises a pressure wire.

52. (New): The assembly of Claim 50, wherein the catheter comprises a sensor for measurement of flow.

53. (New): The assembly of Claim 50, wherein the wire comprises a guide wire.

54. (New): The assembly of Claim 50, wherein the catheter comprises a guide catheter.

55. (New): The assembly of Claim 50, wherein the wire and catheter are dimensioned so that a first solution can be infused through the tube lumen.

56. (New): The assembly of Claim 55, wherein the first solution comprises an NaCl solution.

57. (New): A system for measuring a cross-sectional area of a targeted treatment site, comprising:

an impedance catheter assembly;

a solution delivery source for injecting a solution through the assembly and into the treatment site;

a constant current source; and

a data acquisition and processing system that receives conductance data from the assembly and determines the cross-sectional area of the treatment site.

58. (New): The system of Claim 57, wherein the assembly comprises:

an elongate wire extending from a proximal wire end to a distal wire end;

a catheter comprising an elongate tube extending from a proximal tube end to a distal tube end, said tube having an exterior surface and defining a tube lumen along the longitudinal axis of the tube, said tube surrounding the wire coaxially;

a first excitation impedance electrode and a second excitation impedance electrode along the longitudinal axis of the wire, both located near the distal wire end, said first excitation electrode comprising a first excitation impedance lead extending from said first excitation electrode to a data acquisition system near the proximal wire end, said second excitation electrode comprising a second excitation impedance lead extending from said second excitation electrode to the data acquisition system; and

a first detection impedance electrode and a second detection impedance electrode along the longitudinal axis of the wire, both located in between the first and second excitation electrodes, said first detection electrode comprising a first detection impedance lead extending from said first detection electrode to the data acquisition system, said second detection electrode comprising a second detection impedance lead extending from said second detection electrode to the data acquisition system.